DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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DePuy Synthes Spine, *a Johnson & Johnson Company* November 19, 2014
Catherine Kilshaw, M.S.
Senior Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K142185
Trade/Device Name: DePuy Synthes Spine EXPEDIUM® Verse Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP, KWQ
Dated: August 21, 2014
Received: August 22, 2014

Dear Ms. Kilshaw:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142185

Device Name
DePuy Synthes Spine EXPEDIUM® Verse Spine System

Indications for Use *(Describe)*
The EXPEDIUM Verse System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDIUM Verse System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used in a posterior percutaneous approach with MIS instrumentation, the EXPEDIUM Verse System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the EXPEDIUM Verse System metallic implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The EXPEDIUM Verse system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date Prepared: November 18, 2014

Submitter: DePuy Synthes Spine
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Contact Person: Catherine Kilshaw
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Trade Name: DePuy Synthes Spine EXPEDIUM® Verse Spine System

Device Class: III

Product Code: NKB OSH KWP KWQ MNH MNI

Common Name: Pedicle Screw Spine System

Classification Name: Pedicle Screw Spinal System

Regulation Number: 21 CFR 888.3070

Primary Predicate Device: K111136 EXPEDIUM® Spine System, VIPER® Spine System, VIPER® 2 Spine System

Additional Predicate Devices: K033901 Merlin Spine System (later re-named EXPEDIUM Spine System)
K070387 EXPEDIUM Spine System

Reference Devices: K091994 MOUNTAINEER LAMINOPLASTY SYSTEM
K124004 NAVIGATED CD HORIZON SOLERA SCREWDRIVERS, TAPS, ILIAC TAPS, LEGACY TAPS

Device Description: The EXPEDIUM® Verse System is designed to provide intraoperative polyaxial to monoaxial conversion. It facilitates easier rod capture and provides a powerful and precise reduction mechanism. Verse is a reduced profile thoracolumbar

implant for use for with wide range of patient statures. EXPEDIUM Verse is a self-contained, efficient, and intuitive instrument system that is compatible with EXPEDIUM 5.5 rods, hooks and mono screws to enhance versatility.

Indications:

The EXPEDIUM Verse System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDIUM Verse System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

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Materials:

Titanium alloy Ti64AlV, Cobalt chromium alloy CoCr

Comparison to Predicate Device:

The substantial equivalence of the subject device to the predicate identified above is based upon the similarity of intended use, design (fundamental scientific technology) materials, performance, sterility and biocompatibility.

Non-clinical Test Summary:

Mechanical testing (using the ASTM 1717 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model standard) was provided in order

to provide data to support a substantial equivalence determination. These tests were performed to characterize the properties and functionality of the screw, as well as to allow comparison with established acceptance criteria.

The following mechanical tests were conducted on the screw:

- Static Compression
- Dynamic Compression
- Static Torsion

Clinical Test Summary: N/A

Conclusion: Based upon the predicate comparison, the intended use, similar technological characteristics and the results of the static compression testing, dynamic compression testing and static torsion testing, the proposed device is substantially equivalent to the predicate device.